

TO: Mail Stop 8 Director of the U.S. Patent and Trademark Office P.O. Box 1450 Alexandria, VA 22313-1450	REPORT ON THE FILING OR DETERMINATION OF AN ACTION REGARDING A PATENT OR TRADEMARK
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In Compliance with 35 U.S.C. § 290 and/or 15 U.S.C. § 1116 you are hereby advised that a court action has been
 filed in the U.S. District Court District of New Jersey on the following ☒ Patents or ☐ Trademarks:

DOCKET NO. 08-2311	DATE FILED 5-14-08	U.S. DISTRICT COURT District of New Jersey
PLAINTIFF SALIX PHARMACEUTICALS, INC., NORGINE B.V. and NORGINE EUROPE B.V.		DEFENDANT NOVEL LABORATORIES, INC.
PATENT OR TRADEMARK NO.	DATE OF PATENT OR TRADEMARK	HOLDER OF PATENT OR TRADEMARK
1 7,169,381	1/30/2007	Norman Barras and Ian David Cox
2		
3		
4		
5		

In the above—entitled case, the following patent(s)/ trademark(s) have been included:

DATE INCLUDED	INCLUDED BY <div style="display: flex; justify-content: space-around; font-size: small;"> • Amendment • Answer • Cross Bill • Other Pleading </div>		
PATENT OR TRADEMARK NO.	DATE OF PATENT OR TRADEMARK	HOLDER OF PATENT OR TRADEMARK	
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In the above—entitled case, the following decision has been rendered or judgement issued:

DECISION/JUDGEMENT

CLERK WILLIAM T. WALSH, CLERK	(BY DEPUTY CLERK) <i>[Signature]</i>	DATE 5/15/08
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Copy 1—Upon initiation of action, mail this copy to Director Copy 3—Upon termination of action, mail this copy to Director
 Copy 2—Upon filing document adding patent(s), mail this copy to Director Copy 4—Case file copy

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ATTORNEYS FOR *Plaintiffs*,
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Norgine B.V. and Norgine Europe, B.V.

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

SALIX PHARMACEUTICALS, INC., NORGINE)
B.V. and NORGINE EUROPE B.V.,)

Plaintiffs,)

v.)

NOVEL LABORATORIES, INC,)

Defendant.)

C.A. No. 08-2311 (FLW)

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Salix Pharmaceuticals, Inc., Norgine, B.V., and Norgine Europe, B.V. allege as follows:

PARTIES

1. Plaintiff Salix Pharmaceuticals, Inc. ("Salix") is a California corporation, having its principle places of business at 1700 Perimeter Park Dr., Morrisville, North Carolina.
2. Plaintiffs Norgine B.V. and Norgine Europe B.V. (collectively "Norgine") are each limited liability companies under the laws of the Netherlands, with principal offices at Hogehilweg 7, 1101 CA Amsterdam ZO, The Netherlands.
3. On information and belief, Defendant Novel Laboratories, Inc. ("Novel") is a Delaware corporation, having its principal place of business at 400 Campus Dr., Somerset, New Jersey.

JURISDICTION AND VENUE

4. This is an action for patent infringement arising under the Patent Laws of the United States (Title 35 of the United States Code) and the Food and Drug Laws of the United States (Title 21 of the United States Code). This Court has subject matter jurisdiction of this action under 28 U.S.C. §§ 1331 and 1338(a).

5. On information and belief, Defendant Novel is subject to personal jurisdiction in the United States District Court for the District of New Jersey.

6. Venue is proper in this judicial district pursuant to 28 U.S.C. §§ 1391(b), 1391(c) and 1400(b).

CLAIM FOR RELIEF – PATENT INFRINGEMENT

7. Salix and Norgine reallege paragraphs 1 through 6 as if fully set forth herein.

8. United States Patent No. 7,169,381 (the “’381 patent”) (a true and correct copy of which is attached hereto as Exhibit A), entitled “Colon Cleansing Compositions and Methods,” issued on January 30, 2007 to Norgine upon assignment from the inventors Norman Barras and Ian David Cox. Norgine is the owner by assignment of the ’381 patent. The ’381 patent claims, *inter alia*, compositions comprising polyethylene glycol, ascorbic acid, salts of ascorbic acid, and sulphates.

9. Salix is the exclusive licensee of the ’381 patent within the United States and its territories and possessions as established by a license agreement between Salix and Norgine (hereinafter referred to as the “License Agreement”). The License Agreement grants Salix the right to sue infringers of the ’381 patent.

10. Salix holds—through exercise of its rights under the License Agreement—an approved New Drug Application (“NDA”) from the FDA for a formulation comprising polyethylene glycol 3350, sodium sulphate, sodium chloride, potassium chloride, sodium ascorbate, and ascorbic acid, which it sells under the name MOVIPREP®.

11. Salix and Norgine received a letter from Novel dated April 2, 2008, described as regarding "MoviPrep; U.S. Patent No. 7,169,381; Notice of Paragraph IV Certifications" ("Novel's Letter"). Novel's Letter states that it has submitted an ANDA to the FDA (designated ANDA No. 90-145), under 21 U.S.C. § 355(j), seeking the FDA's approval to manufacture, offer to sell, and sell a product containing the active ingredients polyethylene glycol 3350, sodium sulphate, sodium chloride, potassium chloride, sodium ascorbate, and ascorbic acid (hereinafter referred to as "Proposed Product") as a generic version of Salix's MOVIPREP® product.

12. On information and belief, Novel has infringed the '381 patent under 35 U.S.C. § 271(e)(2), by, *inter alia*, submitting an Abbreviated New Drug Application ("ANDA") to the United States Food and Drug Administration ("FDA") and by generally seeking approval to manufacture, market, and offer to sell its Proposed Product prior to the expiration of the '381 patent.

13. Novel's Letter asserts that, as part of its ANDA, Novel filed a certification of the type described in, and required by, 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (a "Paragraph IV Certification") with respect to the '381 patent. The statute requires, *inter alia*, certification to the FDA by the ANDA applicant that the subject patent, here the '381 patent, "is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted" 21 U.S.C. § 355(j)(2)(A)(vii)(IV). The statute also requires that the ANDA applicant notify the holder of the corresponding NDA that the ANDA applicant has filed a Paragraph IV Certification, 21 U.S.C. § 355 (j)(2)(B)(iii)(II)), and that the notice to the NDA holder provides "a detailed statement of the factual and legal basis of the opinion of the applicant that the patent is invalid or will not be infringed," 21 U.S.C. § 355 (j)(2)(B)(iv)(II). The FDA rules and regulations specify, *inter alia*, that the notice to the NDA holder must include: "[a] detailed statement of the factual and legal basis of the applicant's opinion that the patent is not valid, unenforceable, or will not be infringed." 21 C.F.R. § 314.95(c). The detailed statement must include "(i) [f]or each claim of a patent alleged not to be infringed, a full and detailed explanation of why the claim is not infringed" and "(ii) [f]or each claim of a patent alleged to be invalid or unenforceable, a full and detailed explanation of the grounds supporting the allegation." 21 C.F.R. § 314.95(c).

14. Novel's Letter does not comply with the statutory provisions and regulations referred to in paragraph 13 above, because it fails to provide "[f]or each claim of [the '381 patent] alleged to be invalid or unenforceable, a full and detailed explanation of the grounds supporting the allegation." Therefore, Novel's Letter fails to provide adequate notice under 21 U.S.C. § 355 (j)(2)(B)(iv)(II) and 21 C.F.R. § 314.95(c).

15. Novel's Letter does not dispute infringement of claims 1-12 or 14-40 of the '381 patent.

16. On information and belief, Novel's Proposed Product is a dry composition for admixture with water.

17. On information and belief, Novel's Proposed Product is a dry composition for admixture with water wherein the dry composition contains, per liter of aqueous solution to be made, 100 grams of polyethylene glycol 3350.

18. On information and belief, Novel's Proposed Product is a dry composition for admixture with water wherein the dry composition contains, per liter of aqueous solution to be made, 4.7 grams of ascorbic acid and 5.9 grams of sodium ascorbate.

19. On information and belief, Novel's Proposed Product is a dry composition for admixture with water wherein the dry composition contains, per liter of aqueous solution to be made, 7.5 grams of sodium sulphate.

20. On information and belief, Novel's Proposed Product is a dry composition for admixture with water wherein the dry composition contains, per liter of aqueous solution to be made, 2.691 grams of sodium chloride.

21. On information and belief, Novel's Proposed Product is a dry composition for admixture with water wherein the dry composition comprises lemon flavoring.

22. On information and belief, Novel's Proposed Product is a dry composition for admixture with water wherein the dry composition comprises a sweetener that is not a metabolic substrate for bacteria in the gut.

23. On information and belief, Novel's Proposed Product is a dry composition for admixture with water wherein the dry composition comprises acesulfame potassium.

24. On information and belief, Novel's Proposed Product is a dry composition for admixture with water wherein the dry composition comprises aspartame.

25. On information and belief, Novel seeks FDA approval to market its Proposed Product with instructions for making a colon cleansing preparation.

26. On information and belief, Novel seeks FDA approval to market its Proposed Product as a colon cleansing composition kit.

27. On information and belief, Novel seeks FDA approval to market its Proposed Product as a colon cleansing composition kit comprising at least two portions.

28. On information and belief, Novel seeks FDA approval to market its Proposed Product as a colon cleansing composition kit comprising at least two portions in which the ascorbic acid and the salts thereof are packaged in a first portion and the other components are packaged in a second portion.

29. On information and belief, Novel's Proposed Product and/or its use to prepare an aqueous solution as directed by Novel falls within the scope of Claims 1-12 and 14-40 of the '381 patent.

30. This is an exceptional case under 35 U.S.C. § 285 and Plaintiffs are thereby entitled to an award of their reasonable attorneys' fees incurred herein.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs Salix and Norgine respectfully request the following relief:

(a) A judgment that Novel has infringed one or more claims of the '381 patent under 35 U.S.C. § 271(e)(2) by submitting Novel's ANDA No. 90-145 to the FDA;

(b) A permanent injunction restraining and enjoining Novel and its officers, agents, attorneys and employees, and those acting in privity or concert with it, from engaging in any further infringement of the '381 patent;

(c) A judgment declaring that the effective date of any approval by the FDA under 21 U.S.C. § 355(j) of Novel's ANDA for Novel's Proposed Product comprising polyethylene glycol 3350, sodium sulphate, sodium chloride, potassium chloride, sodium ascorbate, and ascorbic acid shall be no earlier than the later of the expiration date of the '381 patent or the expiration date of any exclusivity to which Plaintiffs are or become entitled;

(d) A judgment declaring that Novel has failed to comply with the requirements of Section 355 of Title 21 of the United States Code, and, in particular, 21 U.S.C. § 355 (j)(2)(B)(iv)(II).

(e) A judgment declaring that Novel has failed to comply with the requirements of the rules and regulations of the United States Food and Drug Administration, and, in particular, 21 C.F.R. § 314.95(c).

(f) A judgment that this is an exceptional case under 35 U.S.C. § 285 and an award to Plaintiffs of their reasonable attorneys' fees;

(g) An award of the costs incurred by Plaintiffs in this action; and

(h) Such other relief as this Court may deem just and proper.

Respectfully submitted,

Dated: May 14, 2008

By: s/ Robert D. Rhoad

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CERTIFICATION PURSUANT TO L. CIV. R. 11.2

Pursuant to L. Civ. R. 11.2, I hereby certify to the best of my knowledge, information and belief that the matter in controversy is not the subject of any other action pending in any court, or of any pending arbitration or administrative proceeding.

Date: May 14, 2008

By: s/ Robert D. Rhoad
Robert D. Rhoad